

This listing of the claims will replace all prior versions, and listings, of claims in the application:

LISTING OF THE CLAIMS

Claim 1 (previously presented): A method for treating premature ejaculation, which comprises administering to a male individual in need of such treatment, less than 3.5 hours prior to anticipated sexual activity, a rapid-release pharmaceutical formulation containing a therapeutically effective amount of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, monoamine oxidase inhibitors, azaspirone antidepressants, and atypical non-SRI antidepressants, wherein the formulation releases the drug at a rate that provides a systemically effective level of the drug within 3.5 hours of administration.

Claim 2 (original): The method of claim 1, wherein the antidepressant drug is contained within a pharmaceutical formulation.

Claim 3 (original): The method of claim 2, wherein the pharmaceutical formulation is a unit dosage form.

Claim 4 (previously presented): The method of claim 2, wherein the antidepressant drug is administered immediately prior to anticipated sexual activity.

Claim 5 (previously presented): The method of claim 1, wherein the antidepressant drug is administered about 0.25 to about 3.5 hours prior to anticipated sexual activity.

Claim 6 (previously presented): The method of claim 5, wherein the antidepressant drug is administered about 0.5 to about 3.0 hours prior to anticipated sexual activity.

Claim 7 (previously presented): The method of claim 6, wherein the antidepressant drug is administered about 1 to about 2.5 hours prior to anticipated sexual activity.

Claim 8 (original): The method of any one of claims 4, 5, 6 and 7, wherein the sexual activity is sexual intercourse.

Claim 9 (currently amended): The method of claim 2, wherein the formulation is a rapid-release ~~an immediate release~~ dosage form.

Claim 10 (currently amended): The method of claim 3, wherein the formulation is a rapid-release ~~an immediate release~~ unit dosage form.

Claim 11 (previously presented): The method of claim 2, wherein the pharmaceutical formulation is administered orally.

Claim 12 (original): The method of claim 11, wherein the pharmaceutical formulation is selected from the group consisting of tablets, capsules, caplets, solutions, suspensions syrups granules, beads, powders and pellets.

Claim 13 (original): The method of claim 12, wherein the pharmaceutical formulation comprises a tablet.

Claim 14 (original): The method of claim 12, wherein the pharmaceutical formulation comprises a capsule.

Claim 15 (previously presented): The method of claim 1, wherein the antidepressant drug is administered transmucosally.

Claim 16 (previously presented): The method of claim 15, wherein the antidepressant drug is administered sublingually.

Claim 17 (previously presented): The method of claim 15, wherein the antidepressant drug is administered buccally.

Claim 18 (previously presented): The method of claim 15, wherein the antidepressant drug is administered intranasally.

Claim 19 (previously presented): The method of claim 15, wherein the antidepressant drug is administered transurethrally.

Claim 20 (previously presented): The method of claim 15, wherein the antidepressant drug is administered rectally.

Claim 21 (previously presented): The method of claim 1, wherein the antidepressant drug is administered by inhalation.

Claim 22 (previously presented): The method of claim 1, wherein the antidepressant drug is administered transdermally.

Claim 23 (original): The method of claim 1, wherein the active agent is administered parenterally.

Claim 24 (original): The method of claim 1, wherein the antidepressant drug is selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressant drugs, and combinations thereof.

Claim 25 (previously presented): The method of claim 24, wherein the antidepressant drug is selected from the group consisting of amitryptiline, amoxapine, butriptyline, demexiptiline, desipramine, dibenzepin, dimetacrine, dothiepin, doxepin, imipramine, iprindole, lofepramine, maprotiline, melitracen, metapramine, mianserin, mirtazapine, nortryptiline, propizepine, protriptyline, quinupramine, setiptiline, tianeptine, trimipramine, and combinations thereof.

Claims 26-27 (canceled).

Claim 28 (previously presented): The method of claim 1, wherein the antidepressant drug is a monoamine oxidase inhibitor.

Claim 29 (previously presented): The method of claim 28, wherein the monoamine oxidase inhibitor is selected from the group consisting of amiflamine, brofaromine, clorgyline,  $\alpha$ -ethyltryptamine, iproclozide, iproniazid, isocarboxazid, mebanazine, moclobemide, nialamide, pargyline, phenelzine, pheniprazine, pirlindole, safrazine, selegiline, toloxatone, tranylcypromine, and combinations thereof.

Claim 30 (previously presented): The method of claim 1, wherein the antidepressant drug is an azaspirone antidepressant.

Claim 31 (previously presented): The method of claim 30, wherein the azaspirone antidepressant is selected from the group consisting of buspirone, gepirone, ipsapirone, tandospirone, tiaspirone, and combinations thereof.

Claim 32 (previously presented): The method of claim 1, wherein the antidepressant drug is an atypical non-SRI antidepressant selected from the group consisting of amesergide, amineptine, benactyzine, bupropion, fezolamine, levoprotiline, medifoxamine, mianserin, minaprine, oxaflozane, oxitriptan, rolipram, teniloxazine, tofenacin, trazodone, tryptophan, viloxazine, and combinations thereof.

Claim 33 (original): The method of claim 1, further comprising administering at least one additional active agent with the antidepressant drug.

Claim 34 (original): The method of claim 33, wherein the additional active agent is a vasoactive agent selected from the group consisting of nitroglycerin, isosorbide dinitrate, erythritol

tetranitrate, amyl nitrate, sodium nitroprusside, molsidomine, linsidomine chlorhydrate, S-nitroso-N-acetyl-d,l-penicillamine, S-nitroso-N-cysteine and S-nitroso-N-glutathione, diazenium diolates ("NONOates"), phenoxybenzamine, dibenamine, doxazosin, terazosin, phentolamine, tolazoline, prazosin, trimazosin, alfuzosin, tamsulosin, indoramin, ergotamine, acetergamine, brazergoline, bromerguride, cianergoline, delorgotrile, disulergine, ergonovine maleate, ergotamine tartrate, etisulergine, lergotrile, lysergide, mesulergine, metergoline, metergotamine, nicergoline, pergolide, propisergide, proterguride, diazoxide, hydralazine, minoxidil nimodepine, pinacidil, cyclandelate, dipyridamole, isoxsuprine, chlorpromazine, haloperidol, yohimbine, prostaglandin E<sub>0</sub>, prostaglandin E<sub>1</sub>, prostaglandin A<sub>1</sub>, prostaglandin B<sub>1</sub>, prostaglandin F<sub>1α</sub>, 19-hydroxy- prostaglandin A<sub>1</sub>, 19-hydroxy- prostaglandin B<sub>1</sub>, prostaglandin E<sub>2</sub>, prostaglandin A<sub>2</sub>, prostaglandin B<sub>2</sub>, 19-hydroxy- prostaglandin A<sub>2</sub>, 19-hydroxy- prostaglandin B<sub>2</sub>, prostaglandin E<sub>3</sub>, prostaglandin F<sub>3α</sub>, carboprost tromethamine, dinoprost tromethamine, dinoprostone, lipoprost, gemeprost, metenoprost, sulprostone, tiaprost, vasoactive intestinal peptide, and combinations thereof.

Claim 35 (original): The method of claim 33, wherein the additional active agent is a phosphodiesterase inhibitor.

Claim 36 (original): The method of claim 35, wherein the phosphodiesterase inhibitor is a Type III, Type IV, Type V, or nonspecific phosphodiesterase inhibitor.

Claim 37 (original): The method of claim 33, wherein the additional active agent is selected from the group consisting of cianopramine, citalopram, femoxetine, fluoxetine, fluvoxamine, ifoxetine, milnacipran, nomifensine, oxaprotiline, paroxetine, sertraline, sibutramine, venlafaxine, viqualine, zimeldine, clovoxamine, etoperidone, methylphenidate, nefazodone, opipramol, 2-methyl serotonin, lysergic acid diethylamide, ergot alkaloids, 8-hydroxy-(2-N,N-dipropylamino)-tetraline, 1-(4-bromo-2,5-dimethoxyphenyl)-2-aminopropane, cisapride, sumatriptan, *m*-chlorophenylpiperazine, zacopride, mezacopride, ondansetron, granisetron, metoclopramide, tropisetron, dolasetron, trimethobenzamide, methysergide, risperidone, ketanserin, ritanserin, clozapine, R(+)--(2,3-dimethoxyphenyl)-1-[2-(4-fluorophenyl)ethyl]-4-

piperidine-methanol, azatadine, cyproheptadine, fenclonine, dexfenfluramine, fenfluramine, chlorpromazine, methoxamine, methpentamine, metaraminol, mitodrine, clonidine, apraclonidine, guanfacine, guanabenz, methyl dopa, amphetamine, methamphetamine, epinephrine, norepinephrine, ethylnorepinephrine, phenylephrine, ephedrine, pseudoephedrine, pemoline, naphazoline, tetrahydrozoline, oxymetazoline, xylometazoline, phenylpropanolamine, phenylethylamine, dopamine, dobutamine, colterol, isoproterenol, isotharine, metaproterenol, terbutaline, tyramine, hydroxyamphetamine, ritodrine, prenalterol, albuterol, isoetharine, pirbuterol, bitolterol, fenoterol, formoterol, procaterol, salmeterol, mephenterine, propylhexedrine, phenoxybenzamine, phentolamine, tolazoline, prazosin, terazosin, doxazosin, trimazosin, yohimbine, labetalol, urapidil, alfuzosin, bunazosin, tamsulosin, haloperidol, phenothiazines, butyrophenones, propranolol, nadolol, timolol, pindolol, metoprolol, atenolol, esmolol, acebutolol, bopindolol, carteolol, oxprenolol, penbutolol, carvedilol, medroxalol, naftopidil, bucindolol, levobunolol, metipranolol, bisoprolol, nebivolol, betaxolol, carteolol, celiprolol, sotalol, propafenone, indoramin, bethanidine, debrisoquine, guabenxan, guanadrel, guanazodine, guanethidine, guanoclor, guanoxan, alprazolam, brotizolam, chlordiazepoxide, clobazepam, clonazepam, clorazepate, demoxepam, diazepam, estazolam, flurazepam, halazepam, lorazepam, midazolam, nitrazepam, nordazepam, oxazepam, prazepam, quazepam, temazepam, triazolam, pharmacologically acceptable salts thereof, and combinations of any of the foregoing.

Claim 38 (original): The method of claim 37, wherein the additional active agent is selected from the group consisting of alprazolam, brotizolam, chlordiazepoxide, clobazepam, clonazepam, clorazepate, demoxepam, diazepam, estazolam, flurazepam, halazepam, lorazepam, midazolam, nitrazepam, nordazepam, oxazepam, prazepam, quazepam, temazepam, triazolam, and pharmaceutically acceptable salts thereof.

Claim 39 (original): The method of claim 37, wherein the additional active agent is selected from the group consisting of fluoxetine, fluvoxamine, paroxetine, sertraline, and pharmaceutically acceptable salts thereof.

Claim 40 (previously presented): A pharmaceutical formulation for treating premature ejaculation, comprising a rapid-release formulation of a therapeutically effective amount of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, MAO inhibitors, azaspirone antidepressants, and atypical non-SRI antidepressants, in an amount effective to delay the onset of ejaculation by the individual during sexual activity, and a pharmaceutically acceptable carrier, wherein the formulation releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration to a patient.

Claim 41 (original): The formulation of claim 40, wherein the antidepressant drug is selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressant drugs, and combinations thereof.

Claim 42 (previously presented): The formulation of claim 41, wherein the antidepressant drug is selected from the group consisting of amitriptyline, amoxapine, butriptyline, demexiptiline, desipramine, dibenzepin, dimetacrine, dothiepin, doxepin, imipramine, iprindole, lofepramine, maprotiline, melitracen, metapramine, mianserin, mirtazapine, nortriptyline, propizepine, protriptyline, quinupramine, setiptiline, tianeptine, trimipramine, and combinations thereof.

Claims 43-44 (canceled).

Claim 45 (original): The formulation of claim 40, wherein the antidepressant drug is selected from the group consisting of monoamine oxidase inhibitors.

Claim 46 (original): The formulation of claim 45, wherein the antidepressant drug is selected from the group consisting of amiflamine, brofaromine, clorgyline,  $\alpha$ -ethyltryptamine, iproclozide, iproniazid, isocarboxazid, mebanazine, moclobemide, nialamide, pargyline, phenelzine, pheniprazine, pirlindole, safrazine, selegiline, tolloxatone, tranylcypromine, and combinations thereof.

Claim 47 (original): The formulation of claim 40, wherein the antidepressant drug is selected from the group consisting of azaspirone antidepressants.

Claim 48 (original): The formulation of claim 47, wherein the antidepressant drug is selected from the group consisting of buspirone, gepirone, ipsapirone, tandospirone, tiaspirone, and combinations thereof.

Claim 49 (original): The formulation of claim 40, wherein the antidepressant drug is an atypical non-SRI antidepressant selected from the group consisting of amesergide, amineptine, benactyzine, bupropion, fezolamine, levoprotiline, medifoxamine, mianserin, minaprine, oxaflozane, oxitriptan, rolipram, teniloxazine, tofenacin, trazodone, tryptophan, viloxazine, and combinations thereof.

Claim 50 (original): The formulation of claim 40, in unit dosage form.

Claim 51 (original): The formulation of claim 50, wherein the antidepressant drug is present in an amount of about 0.1 mg to about to about 300 mg.

Claim 52 (previously presented): The formulation of claim 51, wherein the amount is in the range of about 1 mg to about 100 mg.

Claim 53 (original): The formulation of claim 52, wherein the amount is in the range of about 1 mg to about 50 mg.

Claim 54 (original): The formulation of claim 40, in the form of a rapidly disintegrating tablet.

Claim 55 (original): The formulation of claim 40, in the form of an effervescent tablet.

Claim 56 (original): The formulation of claim 40, in the form of an open matrix network tablet.



Claim 57 (original): A formulation of claim 40, adapted for transmucosal drug administration, wherein the carrier is suitable for transmucosal drug delivery buccally, sublingually, intranasally, rectally, or by inhalation.

Claim 58 (original): The formulation of claim 57, comprising a solid dosage form for application to the buccal mucosa, and wherein the carrier is suitable for buccal drug delivery.

Claim 59 (original): The formulation of claim 58, wherein the carrier is a hydrolyzable polymer.

Claim 60 (original): The formulation of claim 59, wherein the dosage form further comprises an adhesive suitable for affixing the dosage form to the buccal mucosa.

Claim 61 (original): The formulation of claim 57, comprising a dosage form for application to the sublingual mucosa, and wherein the carrier is suitable for sublingual drug delivery.

Claim 62 (original): The formulation of claim 57, comprising a dosage form for application to the rectal mucosa, and the carrier is suitable for rectal drug delivery.

Claim 63 (original): The formulation of claim 62, comprising a rectal suppository.

Claim 64 (original): The formulation of claim 57, comprising a dosage form suitable for inhalation.

Claim 65 (original): The formulation of claim 64, comprising a liquid.

Claim 66 (original): The formulation of claim 64, comprising a dry powder.

Claim 67 (original): The formulation of claim 64, comprising an aerosol composition.

Claim 68 (original): The pharmaceutical formulation of claim 40, comprising an intranasal solution.

Claim 69 (original): The formulation of claim 40, in the form of a gum.

Claim 70 (original): The formulation of claim 40, in the form of a transdermal drug delivery device adapted to be affixed to an individual's body surface.

Claim 71 (previously presented): A packaged kit for a patient to use in the treatment of premature ejaculation, comprising: a rapid-release pharmaceutical formulation of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, MAO inhibitors, azaspiron antidepressants, and atypical non-SRI antidepressants, wherein the formulation releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration to a patient; a container housing the pharmaceutical formulation during storage and prior to administration; and instructions for carrying out drug administration in a manner effective to treat premature ejaculation.

Claim 72 (original): The packaged kit of claim 71, wherein the pharmaceutical formulation is a rapid-release dosage form containing a unit dosage of the antidepressant drug, the unit dosage being a therapeutically effective dosage for treatment of premature ejaculation.